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| 10/528,056 | 03/15/2005 | Josef Seidl | 23241 | 9037 |

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| EXAMINER | |
|---|---|
| HOBBS, MICHAEL L | |

| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/528,056 | SEIDL ET AL. | |
| | Examiner | Art Unit | |
| | MICHAEL HOBBS | 1797 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Specification*

1. The disclosure is objected to because of the following informalities: the preliminary amendment filed on 15 March 2005 “Cross Reference to Related Applications” appears to have an error. The amendment states that the PCT application from which the instant application depends, PCT/EP2002/01358 claims priority to itself, PCT/EP2002/010358.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, applicant states in claim 1 f lines 2-3 and claim 13 line 7 that the device is for "a permanent measuring of all relevant cell culture parameters". It is unclear what is the relevant cell culture parameters that applicant is measuring (i.e. pH, temperature, culture medium flow rate, fluorescence).

4. Claim1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation “cultivating cells of the most diverse type", and the claim also recites “particularly human or animal cells” which is the narrower statement of the range/limitation.

6. Regarding claim 1, the phrase "and the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "and the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 13 provides for the use of a "device for an indirect co-cultivation", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

10. Appropriate corrective action is required.

### *Claim Rejections - 35 USC § 102*

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-7 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kearney (US 5,424,209).

13. For claim 1, Kearney discloses an automated cell culture device that includes a bioreactor or cell culture chamber includes a heating element or incubation equipment for cultivating cells (col. 5 lines 59-62; col. 6 lines 24-26). The bioreactor and heating element are fully capable of adjusting the conditions within the bioreactor to individual cell lines if needed.

14. Regarding claim 2, Culture media is sent to the bioreactor from sample reservoirs (2) via fluid pathways where the nutrient media is oxygenated by a gas source such as a pressurized gas bottle (col. 6 lines 1-3, 12-14). The nutrient media and gas source are fully capable of providing a continuous source of culture media and gas to the bioreactor. Furthermore, the heating of the bioreactor is controlled by a heat sink with a Peltier-type heating/cooling unit that includes an embedded heat sensor for monitoring temperature (col. 6 lines 24-26). The temperature sensor is connected to an on-board computer or controller that controls the operation of the Peltier heating/cooling device (col. 6 lines 27-30). Morphological analysis of the cells occurs through an automated microscope or CCD camera system (col. 20 lines 25-28). Also, cell parameters such as dissolved oxygen content of the media or acidity are sensed by flow cell electrodes within the flow cell (col. 15 lines 32-34). The data from these electrodes form the basis for software controlled decisions to refresh the volume of gas within the oxygentator (col. 15 lines 34-37, oxygenator 6). The computer and software are fully capable of optimizing the conditions within the bioreactor based on feedback from the sensors.

15. With regards to claims 3 and 4, Kearney discloses that the bioreactors are connected in series (col. 20 lines 43-45) or in parallel (col. 6 lines 1-2).

16. For claim 4, Kearney also discloses a circulating peristaltic pump for circulating the media through the plurality of pathways (col. 5 lines 63-67) and for claim 5, Kearney further discloses that the gas flow is controlled by a series of T-unions (38,112) that direct the airflow through a high pressure valve and into a membrane oxygenator (oxygenator 6; col. 14 line 66 through col. 15 line 4). Regarding claim 7, the embedded temperature system was discussed above.

17. With regards to claim 9, Kearney discloses monitoring the cells by a CCD camera which is being interpreted as a video-supported camera.

18. For claim 10, Kearney discloses a computer to control the action of the bioreactor which receives data from the sensors such as microscopic observation of the cells, temperature measurement and measuring cell parameters such as pH . The computer uses this data to control the reaction as was discussed above. Also, for claim 11, data from the sensors was analyzed by soft-ware as was discussed above.

19. Regarding claim 12, Kearney further discloses that bioreactors are mounted within recess of the aluminum heat sink that includes the heating element (col. 6 lines 24-26).

20. Finally for claim 13, Kearney discloses using an automated cell culture device that includes a bioreactor or cell culture chamber includes a heating element or incubation equipment for cultivating cells (col. 5 lines 59-62; col. 6 lines 24-26) where the bioreactors are connected in series (col. 20 lines 43-45).

21. Therefore, Kearney meets the limitations of claims 1-7 and 9-13.

***Claim Rejections - 35 USC § 103***

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

24. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

25. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kearney (US 5,424,209) in view of Pfaller (US 6,329,195 B1).

26. Kearney is silent regarding a gas-permeable membrane with cells on both sides of the membrane.

27. Pfaller discloses a cell culture for continuously supplying culture media to the cells via inflow and outflow openings. For claim 8, Pfaller discloses that the culture chamber is divided by a gas-permeable membrane (5) where the membrane can culture to mono-layers of cells. The inlets and outlets provide for the continuous and homogeneous replacement of culture medium (col. 2 lines 55-58). Also, two different nutrient compositions can be perfused through the top (apical) and bottom (basal) side of the growth support (col. 2 lines 58-62). Since Pfaller discloses that two different culture media can be perfused through the culture chamber, it would be obvious to one of ordinary skill in the art to employ the double chamber of Pfaller in order to co-culture the cells within Kearney. The suggestion for doing so at the time would have been in order to provide organotypic culture conditions within the chamber (col. 2 line 62).

## ***Conclusion***

28. Claims 1-13 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/M.H./
MLH